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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/026,967	12/19/2001	David Bebbington	VPI/00-130-02	1802

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EXAMINER	
TRUONG, TAMTHOM NGO	

ART UNIT	PAPER NUMBER
1624	

DATE MAILED: 01/22/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/026,967	BEBBINGTON ET AL.	
	Examiner	Art Unit	
	Tamthom N. Truong	1624	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *20 November 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-21,23-27 and 29-39* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *1-18* is/are allowed.

6)☒ Claim(s) *19-21,23-27,29 and 32-39* is/are rejected.

7)☒ Claim(s) *30, and 31* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

13)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

a) ☐ The translation of the foreign language provisional application has been received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Applicant's amendment of 11-20-03 has been considered. As per applicant's request, method claims 19-39 are now rejoined with the compound claims 1-18. Thus, the previous restriction is withdrawn herein. The amended claims and argument have overcome the previous rejections of 112/1st and 2nd paragraphs, and thus, they are withdrawn herein. However, the rejoinder of claims 19-39 prompts the following rejection of "Scope of Enablement".

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

1. **Scope of Enablement:** Claims 19-21, 23-27, 29, and 32-39 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the treatment of diabetes, or lowering blood levels of glucose, does **not** reasonably provide **enable**ment for the treatment of other diseases such as: **cancer, osteoporosis, viral disease, autoimmune disease, AML, MS, schizophrenia, baldness, Parkinson's disease, Huntington's disease, cardiomycete hypertrophy, cystic fibrosis, hepatomegaly, neurodegenerative disorders,** etc. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

The following factors have been considered in the determination of an enabling disclosure:

(1) The breadth of the claims;

(2) The amount of direction or guidance presented;

(3) The state of the prior art;

(4) The relative skill of those in the art;

(5) The predictability or unpredictability of the art;

(6) The quantity of experimentation necessary;

[See ***Ex parte Forman***, 230 USPQ 546 (Bd. Pat. App. & Int., 1986); also ***In re Wands***, 858 F. 2d 731, 8 USPQ 2d 1400 (Fed. Cir. 1988)].

a. The breadth of the claims: Claims 19-21, 26, 27, 32-36, 38 are drawn to methods of inhibiting Aurora-2, GSK-3, Src, ERK-2, AKT, or inhibiting the production of hyperphosphorylated Tau protein, or inhibiting the phosphorylation of β-catenin. Said methods cover the treatments of several diseases listed in claims 23, 29, 35, 37, and 39. However, it is noted that the treatment of one disease could be contraindicated in another, or, certain diseases are not associated with Aurora-2, GSK-3, Src, ERK-2, AKT, Tau protein, or β-catenin.

That is, for a compound to treat cancers, it would have to inhibit cell growth somehow. Such a mechanism would cause the loss of hairs, a low number of white blood cells and red blood cells, which makes patients become susceptible to viral, fungal and

bacterial infections. Thus, it would be impossible for a drug to treat cancers, and baldness, viral, and autoimmune diseases. Likewise, the inhibition of cell growth in cancer treatment could not treat neurodegenerative diseases because such a treatment would damage neurons as well.

For other diseases such as: **osteoporosis, AML, MS, schizophrenia, Parkinson's disease, Huntington's disease, cardiomycete hypertrophy, cystic fibrosis, hepatomegaly,** they have etiologies that are not known to be associated with Aurora-2, GSK-3, Src, ERK-2, AKT, Tau protein, or β-catenin. For example, osteoporosis is related to the high activity of osteoclasts which causes bone resorption. Parkinson's disease is known to be associated with dopamine receptor. Other diseases such as: AML, MS, schizophrenia, Huntington's disease have no known cause. Likewise, cardiomycete hypertrophy and hepatomegaly are caused by an increase in cell-size rather than cell numbers. Thus, lowering blood glucose level, or inhibiting Aurora-2, GSK-3, Src, ERK-2, AKT, Tau protein, or β-catenin would necessary treat anything other than diabetes.

b. The amount of direction or guidance presented: The specification shows the inhibitory activity for Aurora-2, GSK-3, and Tau protein. However, it does not provide any evidence for the treatment of **osteoporosis, AML, MS, schizophrenia, Parkinson's disease, Huntington's disease, cardiomycete hypertrophy, cystic fibrosis, hepatomegaly, baldness, viral disease, autoimmune disease, cancers.**

c. **The state of the prior art:** Currently, in the pharmaceutical area, there is no one drug that can treat a variety of disorders that are so unrelated to each other. Particularly, for neurological disorders such as: AML, MS, schizophrenia, Huntington's disease, there is not even an effective drug.

Therefore, with **an unpredictable nature of the art**, and the treatments of a vast number of unrelated disorders, it would require undue experimentation for a skilled clinician to safely and effectively administer the claimed compounds in patients.

Claim Objections

2. Claims 30 and 31 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Allowable Subject Matter

3. Claims 1-18 are allowable since the prior arts of record do not teach a compound of a fused pyrimidine ring substituted with a pyrazolyl-amino.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Tamthom N. Truong whose telephone number is 703-305-4485. The examiner can normally be reached on M-F (9 am - 5:30 pm) starting from January 12th, 2004.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mukund Shah can be reached on 703-308-4716. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4556 for regular communications and 703-308-4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

T. Truong
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January 19, 2004

Acting SPE
Art Unit 1624